IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION NO. 1:18-CV-575

AMGEN INC.,	)
	)
Plaintiff,	)
	)
v.	)
	)
ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD.,	)
	)
Defendants.	)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendants Accord Healthcare, Inc. (a/k/a Accord Healthcare Inc., USA) and Intas Pharmaceuticals Limited (collectively, "Defendants") alleges as follows:

PARTIES

1. Amgen is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Upon information and belief, Defendant Accord Healthcare, Inc. ("Accord") is a North Carolina corporation, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703. Upon information and belief, Defendant Accord is a wholly owned subsidiary of Intas Pharmaceuticals Limited.

3. Upon information and belief, Defendant Intas Pharmaceuticals Limited ("Intas") is an Indian corporation, having a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

4. Upon information and belief, Accord is an agent or affiliate of Intas, and is acting as the agent of Intas with respect to Abbreviated New Drug Application ("ANDA") No. 211892.

5. Upon information and belief, Defendants regularly act in concert to transact business throughout the United States and within North Carolina and this judicial district, including but not limited to marketing, distribution, sales, and/or offers to sell generic drugs.

NATURE OF THE ACTION

6. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent").

7. This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.* and arises out of Accord's filing of ANDA No. 211892 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("Defendants' ANDA products") prior to the expiration of the '405 patent, which is assigned to Amgen and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering SENSIPAR®.

JURISDICTION AND VENUE

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has jurisdiction over Accord because, *inter alia*, upon information and belief, Accord is a North Carolina corporation, is registered to do business as a domestic corporation in North Carolina, is registered with the Food & Drug Protection Division of North Carolina for a drug license under license number 380, has a principal place of business in North Carolina in this judicial district, and has a registered agent for service of process in North Carolina. Upon information and belief, Accord directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including North Carolina, and North Carolina and this judicial district would be a destination of Defendants' ANDA products. Upon information and belief, Accord acted in concert with and/or with the assistance of Intas to file ANDA No. 211892. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in North Carolina and this judicial district, upon approval of ANDA No. 211892, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of North Carolina and this judicial district.

10. This Court has jurisdiction over Intas because, *inter alia*, upon information and belief, Intas is registered to do business as a foreign corporation in North Carolina and has a registered agent for service of process in North Carolina and this judicial district. Upon information and belief, Intas directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including North Carolina, and North Carolina and this judicial district would be a destination of Defendants' ANDA products. Upon information and belief, Intas acted in concert with and/or with the assistance of Accord to file ANDA No. 211892. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in North Carolina and this judicial district, upon approval of ANDA No. 211892, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of North Carolina and this judicial district.

11. In the alternative, this Court has jurisdiction over Intas because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Intas because, *inter alia*, this action arises from actions of Intas directed toward North Carolina and this judicial district and because Intas has purposefully availed itself of the rights and benefits of North Carolina law by engaging in systematic and continuous contacts with North Carolina and this judicial district. Upon information and belief, Intas regularly and continuously transacts business within the State of North Carolina and this judicial district, including by selling pharmaceutical products in North

Carolina and this judicial district, either on its own or through affiliates. Upon information and belief, Intas derives substantial revenue from the sale of those products in North Carolina and this judicial district and has availed itself of the privilege of conducting business within the State of North Carolina and this judicial district.

12. This Court has jurisdiction over Accord and Intas because, *inter alia*, upon information and belief, Accord and Intas have previously been sued in this jurisdictional district without objecting on the basis of lack of personal jurisdiction and have availed themselves of North Carolina courts through the assertions of counterclaims in suits brought in the Middle District of North Carolina. *See e.g.*, *The Medicines Company v. Accord Healthcare, Inc. et al.*, Civil Action No. 14-626 (M.D.N.C.); *Hospira, Inc. et al. v. Intas Pharmaceuticals Ltd. et al.*, Civil Action No. 14-336 (M.D.N.C.); *Eli Lilly & Co. v. Accord Healthcare, Inc.*, Civil Action No. 11-261 (M.D.N.C.).

13. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b). Specifically, venue is proper because Accord is incorporated in North Carolina in this judicial district, and Intas being an Indian corporation may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

THE PATENT-IN-SUIT

14. On June 28, 2016, the ’405 patent, titled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”).

15. The ’405 patent is assigned to Amgen and Amgen is the owner of the ’405 patent.

16. Amgen is the holder of an approved New Drug Application (“NDA”) No. 21-688 for cinacalcet hydrochloride tablets which the U.S. Food and Drug Administration (“FDA”) approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

17. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

18. The ’405 patent is listed in the Orange Book for NDA No. 21-688.

19. The claims of the ’405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

20. Cinacalcet hydrochloride is the active ingredient in SENSIPAR®, a medication marketed and sold in tablet form by Amgen. Amgen received FDA approval to market SENSIPAR® (cinacalcet hydrochloride) on March 8, 2004 to treat secondary

hyperparathyroidism ("HPT") in patients with chronic kidney disease ("CKD") on dialysis and hypercalcemia in patients with parathyroid carcinoma.

21. Secondary HPT is a condition that is caused when the parathyroid glands located in the neck produce too much parathyroid hormone in response to low blood calcium and is associated with CKD patients. SENSIPAR® helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

22. SENSIPAR® is also indicated for use in lowering calcium levels in the blood for patients with parathyroid cancer. Patients with parathyroid cancer can develop severe hypercalcemia (an excessive amount of calcium in the blood). Removal of the parathyroid was the only available therapy for parathyroid cancer before SENSIPAR®.

23. SENSIPAR® is a first-in-class molecule developed by scientists to treat an unmet need in patients suffering from secondary HPT and parathyroid carcinoma.

24. On February 25, 2011, Amgen also received FDA approval to market SENSIPAR® to treat severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

25. Upon information and belief, Defendants reviewed certain commercial and economic information regarding Amgen's SENSIPAR® and decided to file an ANDA seeking approval to market a generic version of SENSIPAR®.

26. Upon information and belief, Defendants collaborated in the research, development, preparation, and filing of ANDA No. 211892 for generic cinacalcet hydrochloride tablets EQ 30 mg, EQ 60 mg, and 90 mg.

27. On May 21, 2018, Amgen received a letter dated May 18, 2018, from Accord notifying Amgen that Accord had filed ANDA No. 211892 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import a generic version of Amgen's SENSIPAR® prior to the expiry of the '405 patent.

28. The stated purpose of Accord's May 18, 2018 letter was to notify Amgen that ANDA No. 211892 included a certification under 21 U.S.C. §355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '405 patent are invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants' ANDA products. Included in the May 18, 2018 letter was a detailed statement of the factual and legal basis for Accord's Paragraph IV Certification.

29. Upon information and belief, Defendants were aware of the '405 patent when Accord notified Amgen of its Paragraph IV Certification of the '405 patent.

30. Amgen commenced this action within 45 days of receipt of the letter.

FIRST CLAIM FOR RELIEF

31. Amgen incorporates and realleges paragraphs 1-30 above, as if set forth specifically here.

32. Upon information and belief, Accord filed ANDA No. 211892 with the FDA under the provisions of 21 U.S.C. § 355(j).

33. Upon information and belief, Accord's ANDA No. 211892 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products (generic cinacalcet hydrochloride tablets, EQ 30 mg, EQ 60 mg, and EQ 90 mg base) before the expiration of the '405 patent.

34. On May 21, 2018, Amgen received a letter from Accord dated May 18, 2108, purporting to be a Notice of Certification for ANDA No. 211892 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

35. Accord's letter alleges that the active ingredient in Defendants' ANDA products for which it seeks approval is cinacalcet hydrochloride.

36. Upon information and belief, Accord has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '405 patent is invalid, not infringed and/or unenforceable.

37. Defendants' submission of ANDA No. 211892 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants'

ANDA products prior to the expiration of the ’405 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, Defendants’ ANDA products would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the ’405 patent.

39. Upon information and belief, Amgen is entitled to full relief from Defendants’ acts of infringement of the ’405 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

40. Amgen incorporates and realleges paragraphs 1-39 above, as if set forth specifically here.

41. Upon information and belief, Defendants have made substantial preparations to sell Defendants’ ANDA products.

42. Upon information and belief, Defendants intend to commence sale of Defendants’ ANDA products immediately upon receiving approval from the FDA.

43. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Defendants’ ANDA products, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the ’405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

44. Amgen will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

45. An actual controversy exists relating to Defendants' threatened infringement of the '405 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amgen respectfully requests the following relief:

A. A judgment that the claims of the '405 patent are not invalid, are not unenforceable, and are infringed by Defendants' submission of ANDA No. 211892 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA products prior to the expiration of the '405 patent will constitute an act of infringement of the '405 patent.

B. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 211892 shall be a date that is not earlier than the expiration date of the '405 patent, inclusive of any extensions.

C. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' ANDA products until after the expiration of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Amgen costs, expenses, and disbursements in this action, including reasonable attorney fees.

E. Such further and other relief as this Court deems proper and just.

MACCORD MASON PLLC

/s/ James L. Lester
James L. Lester (NC Bar No. 15715)
1600 Wells Fargo Tower
300 N. Greene St.
Greensboro, NC 27401
Telephone: (336) 273-4422
E-mail: jlester@maccordmason.com

Attorneys for Amgen Inc.

OF COUNSEL:

John D. Murnane
Joshua I. Rothman
Alicia A. Russo
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

Wendy A. Whiteford
Lois M. Kwasigroch
Eric M. Agovino
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-1000